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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,174	10/12/2000	Hilary Koprowski	JEFF-KOP01.P	2234

7590 07/15/2003

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EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/15/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,174	KOPROWSKI ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response dated April 21, 2003 is acknowledged and entered. Claims 1-16 are pending. Claims 5-16 are withdrawn from consideration being drawn to non-elected subject matter. Claims 1-4 are examined.

Response to Arguments

2. The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Donson *et al* (5,316,931) in view of Ma *et al* (*Eur. J. Immunol.* 1994), Goodman *et al* (4,956,282) and Donson *et al* (*PNAS USA* 1991), is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade.

Applicant mainly argues that:

- Donson (5,316,931) fails to suggest the use of a two vector system. Applicant cites Donson (col. 3) as evidence that only one vector was taught for Donson's system of systemically expressing foreign genes in plants using viral vectors. Applicant argues that one of ordinary skill in the art would have been lead to produce a full antibody in one vector according to Donson's teachings, as opposed to Applicant's claims which use two vectors to express separate chains of the antibody that are later assembled in the plant.
- In response, the Office recognizes that the teachings of Donson are directed to the use of one vector. However, one cannot show nonobviousness by addressing references individually where the rejections are based on combinations of references. Ma teaches the assembly of

monoclonal antibodies in transgenic plants. The missing element in Ma is the use of vectors. The motivation to combine is found in Donson ('931) which teaches that viral vectors are advantageous over transgenics.

- The supposed motivation in Donson ('931) to use vectors over transgenics, is not supported by Donson *et al* (PNAS USA 1991) or Ma *et al* (Eur. J. Immunol. 1994). Applicant points to Donson (1991) which reports low-level expression of foreign sequences (less complex than antibodies) using a viral vector system. Applicant also points to Ma which uses transgenic plants to produce the antibodies, not vector systems.

- In response, the Office recognizes the teachings of Donson (1991) with regard to low-level expression of foreign sequences using vector systems. However, this does not preclude one of ordinary skill in the art from using a vector system. The vector system is taught, used and promoted by Donson ('931). Regarding the teachings of Ma, there is no statement leading one away from using a vector system. Ma's use of a transgenic system versus a vector system does not preclude the use of a vector system.

Conclusion

3. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number

Art Unit: 1648

for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy B. Chen

Stacy B. Chen
July 9, 2003

James C. Housel
JAMES HOUSEL 7/14/03
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TECHNOLOGY CENTER 1600